

Summary of Proposed Regulation Changes

KAR 129-5-1 re: Prior Authorization

This regulation is being modified to place additional drugs on prior authorization. The drugs are:

Buprenorphine/Naloxone (Suboxone)

Buprenorphine (Subutex)

KHPA Fraud and Abuse Unit brought the two drugs listed above to our attention because beneficiaries were receiving prescriptions for these drugs from out of state providers in states as far away as California and Hawaii. Suboxone and Subutex are Schedule II narcotics used in the treatment of opioid dependence. When KHPA looked into beneficiaries getting these medications, it was found that they were getting escalating doses up to 80mg/day. The beneficiaries were also receiving other narcotic prescriptions from other physicians. A physician who specializes in substance abuse addiction reported to the DUR Board that the drug should be placed on prior authorization with a limit of no more than 40mg/day. Prior authorization of these drugs will help ensure coordination of care for the beneficiaries and will address any potential fraud and abuse issues.

Exenatide (Byetta)

The DUR Board recommended prior authorization of this drug because of inappropriate utilization. This drug is indicated for adjunctive therapy of Type 2 diabetes with documented inadequate glycemic control with combination therapy of metformin and/or sulfonylurea. The drug is to be given as an adjunct to other oral antidiabetic drugs. KHPA's review found that beneficiaries were using the drug without a diagnosis for Type 2 diabetes and were on monotherapy. It appears that some beneficiaries were using this medication inappropriately for weight loss. This drug is very expensive.

Pramliditide Acetate (Symlin)

The DUR Board recommended prior authorization of this drug to ensure appropriate patient selection and utilization. The drug carries a Black Box Warning that says pramliditide acetate is used with insulin and has been associated with an increased risk of insulin-induced severe hypoglycemia, particularly in patients with Type 1 diabetes and serious injuries may occur. Proper patient selection is critical to safe and effective use of this drug. This drug is also very expensive.

Fiscal Impact

It is expected that this change will reduce Medicaid expenditures by \$65,600 SGF and \$98,400 FFP, annually.

Public Comment and Expected Reaction

No public comments were received. This action is not considered controversial.

Approval Timeline

Date reviewed by Drug Utilization Review Board: 07/12/06

Date considered by Medicaid staff: 07/31/06

Date published in Kansas Register: 8/17/06

Date approved by KHPA executive staff: 10/05/06

129-5-1. Prior authorization. (a) Any medical service may be placed by the ~~director of health policy and finance~~ Kansas health policy authority on the published list of services requiring prior authorization or precertification for any of the following reasons:

(1) To ensure that provision of the service is medically necessary;

(2) to ensure that services that ~~may~~ could be subject to overuse are monitored for appropriateness in each case; and

(3) to ensure that services are delivered in a cost-effective manner.

(b) Administration of covered pharmaceuticals in the following classes shall require prior authorization. A cross-reference of generic and brand names shall be made available upon request:

(1) Ace inhibitors:

(A) Fosinopril;

(B) moexipril;

(C) perindopril;

(D) ramipril; and

(E) trandolopril;

(2) acne and skin lesion products:

(A) Tretinoin; and

(B) alitretinoin;

- (3)___adjunct antiepileptic drugs:
- ___(A)___Gabitril; and
- ___(B)___zonegran;
- (4) angiotensin II receptor antagonists:
- (A) Candesartan;
- (B) candesartan-HCTZ;
- (C) eprosartan;
- (D) eprosartan-HCTZ;
- (E) olmesartan; and
- (F) olmesartan-HCTZ;
- (5) anticholinergic urinary incontinence drugs:
- (A) Flavoxate;
- (B) oxybutynin XL;
- (C) tolterodine;
- (D) oxybutynin patches; and
- (E) trospium chloride;
- (6) antipsoriatics: alefacept;
- (7) antiretroviral drugs: enfuvirtide;
- (8) antirheumatics:
- (A) Leflunomide;
- (B) infliximab;
- (C) anakinra;

- (D) adalimumab;
- (E) etanercept; and
- (F) abatacept;
- (9) cervical dystonias: botulinum toxins A and B;
- (10) drugs for the treatment of osteoporosis: teriparatide;
- (11) antituberculosis products:
 - (A) Aminosalicylate sodium;
 - (B) capreomycin;
 - (C) ethambutol;
 - (D) ethionamide;
 - (E) isoniazid;
 - (F) pyrazinamide; and
 - (G) rifampin and rifampin-isoniazid combinations;
- (12) all decubitus and wound care products;
- (13) all intravenous and oral dietary and nutritional products, including the following:
 - (A) Amino acids, injectable;
 - (B) l-cysteine;
 - (C) lipids, injectable; and
 - (D) sodium phenylbutyrate;
- (14) beta-blockers:
 - (A) Betaxolol;

- (B) bisoprolol;
- (C) carteolol;
- (D) nadolol;
- (E) penbutolol;
- (F) timolol; and
- (G) propranolol XL;

(15) calcium channel blockers:

(A) Diltiazem extended release, with the following brand names:

- (i) Cardizem SR®;
- (ii) Cardizem CD®;
- (iii) Cartia XT®;
- (iv) Dilacor XR®;
- (v) Taztia XT®; and
- (vi) Cardizem LA®;

(B) verapamil sustained release, with the following brand names:

- (i) Covera HS®; and
- (ii) Verelan PM®;

(C) nifedipine sustained release, with the following brand names:

- (i) Nifedical XL®; and

- (ii) Procardia XL[®] and all generic equivalents;
- (D) nimodipine;
- (E) nisoldipine;
- (F) felodipine;
- (G) isradipine;
- (H) nicardipine SR; and
- (I) nifedipine immediate release, with the following brand names:
 - (i) Adalat[®] and all generic equivalents; and
 - (ii) Procardia[®] and all generic equivalents;
- (16) __fibrin acid derivatives:
 - ____ (A) Antara[®];
 - ____ (B) Lofibra[®];
- (17) __all growth hormones and growth hormone stimulating factor, including the following:
 - (A) Somatrem;
 - (B) somatropin;
 - (C) sermorelin; and
 - ____ (D) mecasermin rinfabate;
- (18) intranasal corticosteroids:
 - (A) Budesonide;
 - (B) Bausch & Lomb's flunisolide;

- (C) beclomethasone; and
- (D) triamcinolone;
- (19) inhaled corticosteroids:
 - (A) Flunisolide-menthol;
 - (B) beclomethasone;
 - (C) QVAR®;
 - (D) triamcinolone;
 - (E) budesonide inhalation powder;
 - (F) budesonide inhaled suspension;
- (20) proton pump inhibitors:
 - (A) ____Esomeprazole;
 - ____(B) omeprazole;
 - (C) omeprazole OTC;
 - ____(D) lansoprazole;
 - (E) pantoprazole; and
 - (F) rabeprazole;
- (21) monoclonal antibody for respiratory syncytial virus (RSV), including palivizumab;
- (22) muscle relaxants:
 - (A) Tizanidine;
 - (B) orphenadrine;
 - (C) methocarbamol;

- (D) carisprodol;
- (E) carisprodol compound;
- (F) cyclobenzaprine (5 mg); and
- (G) metaxolone;

(23) narcotics:

(A) Buprenorphine-naloxone; and

(B) buprenorphine;

(24) nonsteroidal, anti-inflammatory drugs:

- (A) Meloxicam;
- (B) indomethacin;
- (C) nabumetone; and
- (D) piroxicam;

~~+(24)+~~ (25) drugs for the treatment of obesity:

- (A) Orlistat;
- (B) sibutramine; and
- (C) phentermine;

~~+(25)+~~ (26) oxazolidinones, including linezolid;

~~+(26)+~~ (27) HMG-CoA reductase inhibitors:

- (A) Pravastatin;
- (B) fluvastatin;
- (C) lovastatin; and
- (D) rosuvastatin;

~~(27)~~ (28) nonsedating antihistamines:

- (A) Desloratidine; and
- (B) fexofenadine;

~~(28)~~ (29) H₂ antagonists: nizatidine;

~~(29)~~ (30) triptans:

- (A) Naratriptan;
- (B) zolmitriptan; and
- (C) frovatriptan;

~~(30)~~ (31) ~~oral~~ antidiabetic drugs:

- (A) Amaryl®;
- (B) Glucotrol XL®;
- (C) Prandin®;
- (D) Precose®;
- (E) Glucophage XR®;
- (F) Glucovance®; and
- (G) Metaglip®;
- (H) exenatide; and

(I) pramlintide acetate;

~~(31)~~ (32) the following types of syringes, penfills, and
cartridges of insulin:

- (A) Humalog®;
- (B) Humalog Mix®;

- (C) ____Humulin R®;
- (D) Humulin N®;
- ____(E) Humulin 70/30®;
- ____(F) Novolog®;
- (G) Novolog Mix®;
- (H) Novolin R®;
- ____(I) Novolin N®;
- ____(J) Novolin 70/30®; and
- ____(K) Velosulin BR®;
- ~~+32+~~ (33) hypnotics: zaleplon;
- ____~~+33+~~ (34) serotonin 5-HT₃ receptor antagonist antiemetics:
 - (A) Kytril®; and
 - (B) Anzemet®;
- ~~+34+~~ (35) influenza vaccines: Flumist®;
- ~~+35+~~ (36) the following drugs if specifically required by the physician, which shall require prior authorization to override maximum allowable cost (MAC) or federal upper limit (FUL) pricing:
 - (A) Clozaril;
 - (B) depakene;
 - (C) tegretol; and
 - (D) coumadin;
- ~~+36+~~ (37) monoclonal antibody for asthma: omalizumab;

~~(37)~~(38) bisphosphonates: ibandronate sodium;

____~~(38)~~(39) ACE inhibitors-calcium channel blockers:

____(A) Enalapriol maleate-felodipine; and

(B) trandolapril-verapamil;

~~(39)~~(40) ophthalmic prostaglandin analogues:

(A) Latanoprost;

(B) bimatoprost; and

(C) unoprostone;

~~(40)~~(41) topical immunomodulators:

(A) Protopic® (topical formulation); and

(B) Elidel®;

~~(41)~~(42) narcotic analgesics: fentanyl lozenge; and

____~~(42)~~(43) tramadol and all opioids, opioid combinations, and skeletal muscle relaxants, at any dose greater than the maximum recommended dose in a 31-day period._____

(c) Failure to obtain prior authorization, if required, shall negate reimbursement for the service and any other service resulting from the unauthorized or noncertified treatment. The prior authorization shall affect reimbursement to all providers associated with the service.

(d) The only exceptions to prior authorization shall be the following:

(1) Emergencies. If certain surgeries and procedures that require prior authorization are performed in an emergency situation, the request for authorization shall be made within two working days after the service is provided.

(2) Situations in which services requiring prior authorization are provided and retroactive eligibility is later established. When an emergency occurs or when retroactive eligibility is established, prior authorization for that service shall be waived, and if medical necessity is documented, payment shall be made.

(e) Services requiring prior authorization shall be considered covered services within the scope of the program, unless the request for prior authorization is denied. (Authorized by ~~K.S.A. 2005 Supp. 39-7,120 and 75-7412~~ L. 2005, Ch. 187, Sec. 45 and K.S.A. 2005 Supp. 39-7,120, as amended by L. 2005, Ch. 187, Sec. 54; implementing K.S.A. 2005 Supp. 39-7,120 and 39-7,121a, as amended by L. 2005, Ch. 187, Sec. 54 and K.S.A. 2005 Supp. 39-7,121a, as amended by L. 2005, Ch. 187, Sec. 56; effective Oct. 28, 2005; amended June 2, 2006; amended Aug. 11, 2006; amended P-_____.)